## REMARKS

After entry of this Amendment, the pending claims are: claims 1, 2, 4-22 and 24-50. The Office Action dated October 18, 2007 has been carefully considered. Claims 3 and 23 were previously canceled without prejudice. Independent claims 1, 34 and 35 have been amended to clarify the scope of protection. Applicants have deleted the limitations previously added in the Response to Non-Final Office Action dated July 10, 2007. In particular, Applicants have deleted the limitation, and the accompanying Remarks distinguishing the prior art based on, inter alia, that the fiber system is guided over the external surfaces of both cover plates, that the sheathing body is made from a homogeneous material, and that the fibre system is at least partially embedded within the elastic sheathing body. As such, these limitations, either alone or in combination, no longer exist and should not be relied upon, as creating an estoppel or otherwise limiting the scope of these claims. Dependent claims 2, 4-22 and 24-33 have been amended without prejudice to correct spelling and grammatical errors. Claims 36-50 have been added. Support for the amendments to claims 1, 2, 4-22, 24-35 and newly added claims 36-50 can be found throughout the Specification and Drawings and specifically in paragraph Nos. 8, 11, 23, 25, 27-35, 38, 57, 58 and originally files claims 13-15, 17 and 18. No new matter has been added. Reconsideration and allowance of the pending claims in view of the above Amendments and the following Remarks is respectfully requested.

In the Office Action dated October 18, 2007, the Examiner:

- rejected claims 1, 2, 6, 7, 8, 11, 13, 19, 28, and 34 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,867,728 to Stubstad *et al.* ("Stubstad");
- rejected claim 32 under 35 U.S.C. 103(a) as being unpatentable over Stubstad in view of U.S. Patent No. 7,066,960 to Dickman ("Dickman");
- rejected claims 1, 4, 5, 9, 10, 12, 14-16, 19, 20, 27, 31 and 33 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,645,248 to Casutt ("Casutt") in view of U.S. Patent No. 6,120,539 to Eldridge *et al.* ("Eldridge");

• rejected claims 17, 18 and 35 under 35 U.S.C. 103(a) as being unpatentable over Casutt in view of Eldridge and in further view of U.S. Patent No. 7,060,097 to Fraser *et al.* ("Fraser");

• rejected claims 21, 22, 24, and 25 under 35 U.S.C. 103(a) as being unpatentable over Casutt in view of Eldridge and in further view of U.S. Published Patent Application No. 2002/0123750 to Eisermann *et al.* ("Eisermann"); and

• indicated that claims 26, 29 and 30 would be allowable if rewritten into independent claim form to include all of the limitations of the base claim and any intervening claims.

## **INDEPENDENT CLAIM 1**

Independent claim 1 has been rejected as being unpatentable over Stubstad. In addition, independent claim 1 has been rejected as being unpatentable over Casutt in view of Eldridge.

As amended, independent claim 1 recites an intervertebral implant for implantation between adjacent vertebrae, the implant having a central axis, the implant comprising: a bottom closing plate having an external surface extending generally transversely to the central axis for contacting at least a portion of one of the adjacent vertebrae; a bottom cover plate in contact with the bottom closing plate, wherein at least one of the bottom closing plate and the bottom cover plate is substantially rigid; a top closing plate having an external surface extending generally transversely to the central axis for contacting at least a portion of the other adjacent vertebrae; a top cover plate in contact with the top closing plate, wherein at least one of the top closing plate and the top cover plate is substantially rigid; a central part provided between the top and bottom closing plates, the central part including a fiber system

and a core, the fiber system being at least partially joined to the cover plates, and at least partially surrounding the core, and a sheathing comprising an elastic sheathing body, the sheathing body at least

partially surrounding the central part and being connected to the top and bottom cover plates.

Stubstad discloses an intervertebral implant including a central element 15, a top element 11 and

silicone elastomer layers 14. The top element 11 includes a bottom layer 17 of silicone elastomer.

Disposed above the bottom layer 17 is a central layer 18 of silicone elastomer and an upper layer 19 of

a bottom element 12. The central element 15 including a central portion 16 surrounded by a plurality of

silicone elastomer. Above the upper layer 19 is one or more layers 20 of a suitable fabric having an open

porous weave to invite tissue ingrowth. A covering or coating 21 is folded across the top layer 20,

preferably in pleats 22. The lower element 12 is preferably exactly the same as the upper element 11,

except that its layers 17', 18', 19', 20' and 21' are in reverse order. In completing the implant 10, after the

elements 11, 15 and 12 have been assembled in that order, the article 10 is stitched together through the

fabric 21 by a filament 29 to join all parts firmly together. Then the assembly is subjected to

vulcanizing heat which acts to weld various surfaces together.

It is respectfully submitted that Stubstad does not disclose, teach or suggest an intervertebral

implant comprising a bottom closing plate and a bottom cover plate in contact with the bottom closing

plate wherein at least one of the bottom closing plate and the bottom cover plate is substantially rigid;

and a top closing plate and a top cover plate in contact with the top closing plate wherein at least one of

the top closing plate and the top cover plate is substantially rigid. Rather, as previously mentioned,

Stubstad discloses a top element 11 and a bottom element 12 wherein the top and bottom elements

15

include a bottom layer of silicone elastomer, a central layer of silicone elastomer, an upper layer of silicone elastomer, and one or more layers of fabric.

Moreover, it is respectfully submitted that Stubstad does not disclose, teach or suggest an intervertebral implant comprising a central part provided between the top and bottom closing plates, the central part including a fiber system and a core, the fiber system being at least partially joined to the cover plates, and at least partially surrounding the core, and a sheathing comprising an elastic sheathing body, the sheathing body at least partially surrounding the central part and being connected to the top and bottom cover plates. Rather, as previously mentioned, Stubstad discloses a central element 15 including a central portion 16 surrounded by a plurality of silicone elastomer layers 14.

Therefore, for at least the above-identified reasons, it is respectfully submitted that Stubstad does not disclose, teach or suggest all of the limitations of independent claim 1. Thus, it is respectfully submitted that independent claim 1 is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested.

In addition, independent claim 1 was rejected as being unpatentable over Casutt in view of Eldridge. It is respectfully submitted that Casutt does not disclose, teach or suggest an intervertebral implant comprising a bottom closing plate having an external surface for contacting at least a portion of one vertebrae; a top closing plate having an external surface for contacting at least a portion of another vertebrae; a bottom cover plate in contact with the bottom closing plate, a top cover plate in contact with the top closing plate, a central part including a fiber system and a core, and a sheathing comprising an elastic sheathing body, the sheathing body at least partially surrounding the central part and being

implanting between two vertebral bodies wherein the artificial intervertebral disc includes two end

plates 1, 2 separated by a hollow space 4, the space 4 being completely filled with an elastically and/or

plastically deformable nucleus 3 and being surrounded by a tubular fiber ring 5 such that the end plates

1, 2 surround the hollow space 4 together with the fiber ring 5.

Moreover, it is respectfully submitted that Eldridge does not overcome the short comings of

Casutt. Eldridge was cited for the proposition that it would be obvious for one of ordinary skill in the art

to incorporate a sheathing body wherein the fiber system is partially embedded into the sheathing body.

It is respectfully submitted that the claim limitation "wherein the fibre system is at least partially

embedded within the elastic sheathing body," has been removed from independent claim 1. Thus,

without addressing the merits of this argument, it is respectfully submitted that, for at least the above-

identified reason, neither Casutt or Eldridge, either alone or in combination, disclose, teach or suggest

all of the limitations of independent claim 1. Thus, it is respectfully submitted that independent claim 1

is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 1

is respectfully requested.

Furthermore, as claims 2, 4-22, 24-33, and newly added dependent claims 40-42 all depend from

independent claim 1, it is submitted that these claims are equally allowable for at least these reasons.

Withdrawal of these rejections and allowance of claims 2, 4-22, 24-33, and 40-42 is also respectfully

requested.

17

Independent claim 34 was rejected as being unpatentable over to Stubstad. As amended,

independent claim 34 recites an intervertebral implant for implantation between first and second

vertebrae, the implant comprising: a top substantially rigid closing plate having an external surface and

an internal surface, the external surface of the top closing plate contacting at least a portion of the first

vertebra when in an implanted position; a bottom substantially rigid closing plate having an external

surface and an internal surface, the external surface of the bottom closing plate contacting at least a

portion of the second vertebra when in the implanted position; a top cover plate in contact with the top

closing plate proximate the internal surface of the top closing plate, the top cover plate having a top

surface and a bottom surface; a bottom cover plate in contact with the bottom closing plate proximate

the internal surface of the bottom closing plate, the bottom cover plate having a top surface and a bottom

surface; a central part located between the internal surfaces of the top and bottom closing plates, the

central part including an elastic core and a fiber system; and an elastic sheathing body, the sheathing

body at least partially surrounding the central part, at least a portion of the fiber system is in contact with

the top cover plate and the bottom cover plate.

It is respectfully submitted that Stubstad does not disclose, teach or suggest an intervertebral

implant comprising a top substantially rigid closing plate having an external surface and an internal

surface, the external surface of the top closing plate contacting at least a portion of the first vertebra

when in an implanted position; a bottom substantially rigid closing plate having an external surface and

an internal surface, the external surface of the bottom closing plate contacting at least a portion of the

second vertebra when in the implanted position; a top cover plate in contact with the top closing plate;

18

element 11 and a bottom element 12 wherein the top and bottom elements include a bottom layer of

silicone elastomer, a central layer of silicone elastomer, an upper layer of silicone elastomer, and one or

more layers of fabric.

Moreover, it is respectfully submitted that Stubstad does not disclose, teach or suggest an

intervertebral implant comprising a central part located between the internal surfaces of the top and

bottom closing plates, the central part including an elastic core and a fiber system; and an elastic

sheathing body, the sheathing body at least partially surrounding the central part, at least a portion of the

fiber system is in contact with the top cover plate and the bottom cover plate.

Therefore, for at least the above-identified reasons, it is respectfully submitted that Stubstad does

not disclose, teach or suggest all of the limitations of independent claim 34. Thus, it is respectfully

submitted that independent claim 34 is allowable over the cited prior art. Withdrawal of this rejection

and allowance of independent claim 34 is respectfully requested.

Furthermore, newly added dependent claims 43-46 all depend from independent claim 34, it is

submitted that these claims are equally allowable for at least these reasons. Allowance of claims 43-46

is also respectfully requested.

**INDEPENDENT CLAIM 35** 

Independent claim 35 was rejected as being unpatentable over Casutt in view of Eldridge and in

further view of Fraser. As amended, independent claim 35 recites an intervertebral implant for

implantation between first and second vertebrae, the implant comprising: a top plate having an external

19

surface and an internal surface; a bottom plate having an external surface and an internal surface; a

central part including a core and a fiber system, the central part located between the internal surfaces of

the top and bottom plates, the fiber system connected to the top and bottom plates and at least partially

surrounding the core, the fiber system including a plurality of interwoven fibers; and an elastic sheathing

body connected to the top and bottom plates, the elastic sheathing body at least partially surrounding the

fiber system.

It is respectfully submitted that Casutt does not disclose, teach or suggest an intervertebral

implant comprising a central part including a core and a fiber system, wherein the fiber system at least

partially surrounds the core, and an elastic sheathing body at least partially surrounding the fiber system.

Rather, Casutt discloses an artificial intervertebral disc for implanting between two vertebral bodies

wherein the artificial intervertebral disc includes two end plates 1, 2 separated by a hollow space 4, the

space 4 being completely filled with an elastically and/or plastically deformable nucleus 3 and being

surrounded by a tubular fiber ring 5 such that the end plates 1, 2 surround the hollow space 4 together

with the fiber ring 5.

Moreover, it is respectfully submitted that Eldridge does not overcome the short comings of

Casutt. Eldridge was cited for the proposition that it would be obvious for one of ordinary skill in the art

to incorporate a sheathing body wherein the fiber system is partially embedded into the sheathing body.

It is respectfully submitted that the claim limitation "wherein at least a portion of the fibre system is

embedded in the elastic sheathing body," has been removed from independent claim 35. Thus, without

addressing the merits of this argument, it is respectfully submitted that, for at least the above-identified

20

limitations of independent claim 35.

Furthermore, it is respectfully submitted that Fraser does not overcome the short comings of

Casutt and Eldridge. Fraser was cited for the proposition that it would be obvious for one of ordinary

skill in the art to incorporate a plurality of grooves on the circumference and radially penetrating into the

lateral surfaces of the top and bottom cover plates. It is respectfully submitted that the claim limitation

"wherein the external surfaces of the top and bottom plates includes a plurality of grooves formed

therein for receiving the fibre system," has been removed from independent claim 35. Thus, without

addressing the merits of this argument, it is respectfully submitted that, for at least the above-identified

reason, neither Casutt or Eldridge or Fraser, either alone or in combination, disclose, teach or suggest all

of the limitations of independent claim 35. Thus, it is respectfully submitted that independent claim 35.

is allowable over the cited prior art. Withdrawal of this rejection and allowance of independent claim 35

is respectfully requested.

Furthermore, newly added dependent claims 36-39 all depend from independent claim 35, it is

submitted that these claims are equally allowable for at least this reason. Allowance of claims 36-39 is

also respectfully requested.

**NEWLY ADDED INDEPENDENT CLAIM 47** 

Newly added independent claim 47 recites an intervertebral implant for implantation between an

upper and lower vertebrae, the implant having a central axis, the implant comprising: a first substantially

rigid bone contacting plate having an external surface extending generally transversely to the central

21

axis for contacting at least a portion of the upper vertebra; a second substantially rigid bone contacting

plate having an external surface extending generally transversely to the central axis for contacting at

least a portion of the lower vertebra; a third plate operatively coupled to the first bone contacting plate,

the third plate including a plurality of openings; a fourth plate operatively coupled to the second bone

contacting plate, the fourth plate including a plurality of openings; a central part substantially located

between the third and fourth plates, the central part including a flexible core and a fiber system, wherein

the core is substantially cylindrical and includes a top surface and a bottom surface, the top surface of

the core being in contact with the third plate and the bottom surface of the core being in contact with the

fourth plate, and wherein the fiber system at least partially surrounds the core, and is at least partially

received within the plurality of openings formed in the third and fourth plates so that the fiber system is

joined to the third and fourth plates; and an elastic sheathing body at least partially surrounding the fiber

system and the core, and connected to the third and fourth plates.

It is respectfully submitted that the cited prior art does not disclose, teach or suggest all of the

limitations of newly added independent claim 47. Thus, it is respectfully submitted that independent

claim 47 is allowable over the cited prior art. Allowance of newly added independent claim 47 is

respectfully requested.

Furthermore, newly added dependent claims 48-50 all depend from independent claim 47, it is

submitted that these claims are equally allowable. Allowance of claims 48-50 is also respectfully

requested.

22

## **CONCLUSION**

A fee of \$1,080.00 is believed due for this submission for the addition of fifteen newly added claims, including one addition independent claim, and for a one month extension of time. The Commissioner is authorized to charge this and any other fee which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicants' attorney at the number listed below.

Respectfully submitted,

Date: February 19, 2008 /Giuseppe Molaro/

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